

AUG 02 2002

K022317

510(k) Summary

for

**DANA Diabecare® II Insulin Pump and SUPERLINE-EasyRelease,
Soft-Release-ST, and Soft-Release-R Infusion Sets**

1. SPONSOR

Sooil Development Co., Ltd.
111-1, Heukseokl-Dong, Dongjak-Ku
Seoul, 156-071
KOREA

Contact Person: Soo Bong Choi
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82-441-845-2128 (Facsimile)

Date Prepared: July 16, 2002

2. DEVICE NAME

Proprietary Name: DANA Diabecare® II Insulin Pump and SUPERLINE-EasyRelease, Soft-Release-ST, and Soft-Release-R Infusion Sets
Common/Usual Name: Insulin infusion pump and infusion set accessories
Classification Name: Infusion pump

3. PREDICATE DEVICES

DANA Diabecare® insulin pump and SUPERLINE infusion set (Sooil Development Co., Ltd., K001604)

4. DEVICE DESCRIPTION

The DANA Diabecare® II insulin pump, SUPERLINE-EasyRelease (EasyRelease) Infusion Set, and Soft-Release Infusion Sets are modifications of the DANA Diabecare® insulin pump and SUPERLINE infusion set that were described in K001604, the 510(k) premarket notification for the DANA Diabecare® insulin infusion pump.

5. INTENDED USE

The DANA Diabecare® II external programmable syringe infusion pump and the SUPERLINE-EasyRelease, Soft-Release-R, and Soft-Release-ST Infusion Sets are indicated for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. The pump and administration sets are not intended for use with blood or blood products.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The modifications made to the parent DANA Diabecare® insulin pump and SUPERLINE Infusion Set to produce the proposed DANA Diabecare® II Insulin Pump and the EasyRelease, Soft-Release-ST, and Soft-Release-R Infusion Sets were implemented to enhance the convenience, ease of use, and comfort of the devices.

The modifications made to the parent DANA Diabecare® insulin pump to produce the modified DANA Diabecare® II Insulin Pump were limited to software modifications including changes to the basal and bolus insulin delivery modes, features accessed via the password-protected (lock-out) mode, and the addition of alarms, a fail-safe function, and the ability to store and retrieve information (alarm, bolus dose, daily insulin dose).

The overall design of the proposed EasyRelease, Soft-Release-ST, and Soft-Release-R Infusion Sets is identical to the design of the parent SUPERLINE Infusion Set. The design modifications are limited to the following:

- Addition of a site for disconnecting the insulin pump from the infusion set without removing the needle from the abdomen
- Replacement of the infusion needle with an indwelling soft cannula (Soft-Release-R and Soft-Release-ST only)

The two versions of the Soft-Release Infusion Sets differ in the design of the detachment site and cannula assembly. The Soft-Release-R Infusion Set has a sliding lock detachment site and a “rectangular” cannula oriented perpendicular to the infusion tubing axis. The Soft-Release-ST has a turning screw lock detachment site that uses a conical fitting and a straight cannula oriented parallel to the infusion tubing axis.

There are minor differences in the materials used for the construction of the proposed EasyRelease, Soft-Release-ST, and Soft-Release-R Infusion Sets as compared to the parent SUPERLINE. Sooil has conducted the necessary testing to satisfy the

biocompatibility requirements of ISO 10993-1 for use as an insulin administration set.

7. PERFORMANCE TESTING

In addition to the biocompatibility testing mentioned in the previous section, design verification activities included burst testing, bioburden testing, insulin potency assay, and shelf-life testing. The results of the burst and bioburden tests confirm that the detachment sites incorporated in the EasyRelease and Soft-Release Infusion Sets do not leak or unexpectedly detach and the fluid path remains sterile following repeated detachment/reattachment procedures. The insulin potency assay indicates that insulin remains stable for up to 120 hours in the EasyRelease and Soft-Release Infusion Sets. The shelf-life testing supported a three-year shelf life for the EasyRelease and Soft-Release Infusion Sets.



AUG 02 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sooil Development Company Limited
Ms. Cynthia J. M. Nolte
Consultant
Medical Device Consultanting, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022317

Trade/Device Name: DANA Diabecare® II Insulin Pump and SUPERLINE-Easy
Release, Soft-Release-ST, and Soft-Release-R Infusion Sets
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: July 16, 2002
Received: July 17, 2002

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K 02 2317


Device Name: DANA Diabecare® II Insulin Pump and SUPERLINE-EasyRelease,
Soft-Release-ST, and Soft-Release-R Infusion Sets

Indications for Use:

The DANA Diabecare® II external programmable syringe infusion pump and the SUPERLINE-EasyRelease, Soft-Release-ST, and Soft-Release-R Infusion Sets are used for the subcutaneous delivery of insulin for the treatment of diabetes mellitus. These devices are not intended for use with blood or blood products.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K022317

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

(Optional Format 1-2-96)